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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/373,403 | 08/12/1999 | WILLIAM R. ARATHOON | P1099C1 | 2534 |
| 23552 | 7590 | 10/24/2005 | EXAMINER | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | BLANCHARD, DAVID J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/373,403

Applicant(s)

ARATHOON ET AL.

Examiner

David J. Blanchard

Art Unit

1643

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 + 2 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 03 October 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 30-43 and 45-55.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

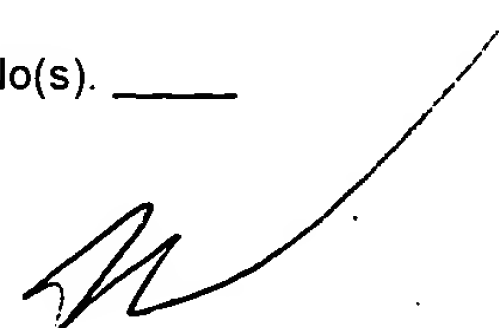
REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

**LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER**



Continuation of 3. NOTE: The amendment filed in 10/3/05 introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment claims priority to Application No. 08/850,058, filed on May 2, 1997, which is incorporated by reference. The priority application cannot be incorporated by reference after the original filing of the instant application. See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003) "Benefit of Prior-Filed Application" (see Part VII).

Further, entry of the amendment would raise new issue, requiring new considerations, new search and new rejections. For example, claim 50 has been amended to recite, "and only differs from each of the common light chains of the first and at least one additional antibody at amino acid positions outside of the CDR regions" wherein the first and at least one additional antibody bind to different antigens. The specification, including the claims, as originally filed, appears to provide written support for a bispecific antibody comprising a variable light chain polypeptide having at least 98% amino acid sequence identity to either a first or a second variable light chain domain of two different antibodies that bind a first or second antigen, respectively, however, it does not appear to provide adequate written support for a bispecific antibody comprising a variable light chain polypeptide having at least 98% amino acid sequence identity to both a first and a second variable light chain domain of two different antibodies that bind a first or second antigen, respectively. This issue might be remedied if Applicant were to point to particular disclosures in the specification, including the claims, as originally filed, that are believed to provide proper written support for the claim language.

Continuation of 5. Applicant's reply has overcome the following rejection(s): If, if, if entered, the response filed 10/3/2005 would overcome the rejections of claims 50, 53-55 under 35 USC 112, first paragraph as introducing new matter; the rejection of claims 51-52 under 35 USC 112, second paragraph for indefiniteness; and the objection to claim 52 under 37 CFR 1.75(c) as being in improper dependent form.

Continuation of 11. does NOT place the application in condition for allowance because: If, if, if entered, the response filed 10/3/2005 would not overcome the rejection of claims 30-42 under 35 USC 112, first paragraph as introducing new matter, essentially for reasons of record. The response again points to pages 95-97 of the specification as providing adequate written support for the present claims. These teachings are directed towards the process whereby applicant discovered scFvs having common light chains can bind two different antigens and the process of selecting a common light chain that will be used for making a multispecific antibody. The teachings at page 97 of the specification do not provide adequate written support for multispecific antibodies having two different light chains (i.e., differ by at least one amino acid), but instead are directed to a process for identifying one common light chain for making a multispecific antibody. Again, the specification defines "common light chain" or "common amino acid sequence of the light" as referring to the amino acid sequence of the light chain in the multispecific antibody of the invention (page 21). The examiner agrees that the specification need not describe *ipsis verbis* what is recited in the claims, however, the specification does not contemplate using two different light chains (i.e., at least 98% identical) in the multispecific antibody as presently claimed. In response to applicant's query as to why the specification does not, at the very least, implicitly support using different light chains in the multispecific antibody, it is respectfully pointed out that obviousness is not the standard for the addition of new limitations to the disclosure as-filed. It is noted that entitlement to a filing date does not extend to subject matter, which is not disclosed, but would be obvious over what is expressly disclosed. *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961 (Fed. Cir. 1977). Further, applicant's arguments noting the teachings in the specification of light chains having at least 98% sequence identity that can bind to either of two antigens in the context of an antigen-binding domain appears to go more towards enablement, however, the instant claims are rejected for lack of adequate written support for the presently claimed subject matter. Applicant is reminded that the description requirement is severable from the enablement requirement.

Additionally, the response filed 10/3/05 does not place the present application in condition for allowance and the provisional rejections of claims 30-43 and 45-49 under the judicially created doctrine of obviousness-type double patenting over the claims in copending applications 09/863,693, 09/520,130 and 10/143,437 are maintained.

Respectfully,
David J. Blanchard
571-272-0827



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